



From the Office of the President

October 11, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

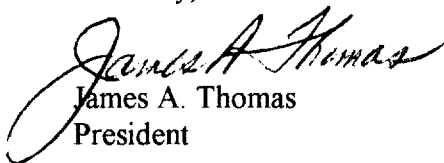
To Whom It May Concern:

We are writing in response to a notice in the Federal Register of Friday, July 30, 1999 regarding a Proposed Rule to Reclassify Surgeon's and Patient Examination Gloves.

Members of ASTM Committee D11 on Rubber have carefully reviewed the proposed rule and request an extension of the comment period.

Thank you for the opportunity to comment.

Sincerely,


James A. Thomas
President

CC: D11 Executive Committee
D11.40 Subcommittee

98N-0313

C7



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Committee D11 on RUBBER

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Subject: Surgeon's and Patient Examination Gloves; Reclassification
21 CFR Parts 801, 878, and 880
Docket Number 98N - 0313
RIN 0910 - AB74

ASTM is a not-for-profit organization that provides a forum for producers, users, ultimate consumers, and those having a general interest (representatives of government and academia) to meet on common ground and write consensus standards for materials, products, systems, and services.

ASTM, on behalf of Committee D11 on Rubber, is submitting this formal request for an extension of the comment period on the FDA's proposed rule; reclassification of surgeon's and patient examination gloves, published in the Federal Register, Vol. 64, No. 146 on Friday, July 30, 1999.

The FDA has asked for comments on 12 specific questions. Question 2 refers to the recommended powder limit of 120 mg per glove. ASTM is currently balloting revisions to published standards D3577-99, D3578-99, D5250-99, and D6319-99 for rubber surgical gloves, rubber examination gloves, polyvinyl medical gloves, and nitrile examination gloves respectively to insert a recommended maximum powder limit. The ASTM ballot closes October 22, 1999. If no negatives are received then these standards will receive an approval date of November 10, 1999 and subsequently be published. If negatives are received, then the ASTM D11.40 subcommittee will resolve these issues at their December 6, 1999 meeting and the standards may be approved soon thereafter.

ASTM requests an extension for a period of 90 days to allow the opportunity for the new standards to be approved.

Sincerely,

Kok-Kee Hon

Kok-Kee Hon
Chairman D11.40

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